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Briefs and Other Related Documents
Only the Westlaw citation is currently available.
United States District Court,D. Delaware.
AMPEX CORPORATION, Plaintiff,
v.
EASTMAN KODAK COMPANY, Altek Corporation, and Chinon Industries, Inc., Defendants.
No. CIV A. 04-1373-KAJ.

July 17, 2006.

MEMORANDUM ORDER

JORDAN, J.

Introduction

*1 This is a patent case, presently set for trial on December 4, 2006. (Docket Item ["D.I."] 53 at ¶ 17.) The plaintiff, Ampex Corporation ("Ampex"), has filed a letter motion (D.I. 268; the "Motion") seeking to compel the defendants, Eastman Kodak Company, Altek Corporation, and Chinon Industries, Inc. (collectively "Kodak"), to disclose "all information communicated to ... [Kodak], or reflecting communications to ... [Kodak], on the same subject matter as their September 2, 2005 opinion of counsel;" and it further seeks an order requiring Kodak to "provide a log of all materials withheld on privilege or work-product grounds dated on or before April 11, 2006, the expiration date of the '121 patent in suit." (*Id.* at 1; D.I. 275 at 1.) In short, Ampex wants all of the attorney-client communications between Kodak and its trial counsel bearing on the subject of infringement, and it wants a log of all withheld materials relating to that subject. At the outset of the claim construction and summary judgment argument on July 13, 2006, I denied the Motion in a bench ruling. This memorandum order further memorializes the bases for that ruling.

Background [FN1]

FN1. The parties appear to be essentially in agreement on the background facts provided here, which are drawn primarily from the statements of fact provided in their letter submissions and briefing.

On April 11, 1989, U.S. Patent No. 4,821,121 (the "'121 patent") issued and was assigned to Ampex. (D.I. 38 at Ex. 1.) It is entitled "Electronic Still Store with High Speed Sorting and Method of Operation." (*Id.*) The claimed invention "relates to a digital electronic still store for broadcast television signals and more particularly to a still store providing a high speed multiimage [sic] scan or sort capability." (*Id.* at col. 1, ll. 11-14.) In 2001, twelve years after the patent issued, and five years after Kodak began selling digital cameras in the consumer electronics market, Ampex wrote to Kodak and invited Kodak to discuss (or, according to one's perspective, demanded that Kodak discuss) licensing the '121 patent.[FN2] (D.I. 275 at 3; D.I. 312 at 3.)

FN2. Kodak notes that, while it entered the consumer market for digital cameras in 1996, it had been selling digital cameras to photography professionals since 1991. (D.I. 312 at 3.) Ampex contends that Kodak was aware of the patent since at least 1992, when an in-house counsel at Kodak came across the patent and flagged it for further study. (*See* D.I. 275 at 3.)

Kodak exchanged letters with Ampex about the '121 patent in 2001 and again in 2004. (Dl. 275 at 3; D.I. 312 at 3-4.) After the first exchange, Kodak's in-house counsel undertook an analysis and, according to Kodak, concluded that Kodak did not infringe the '121 patent. (D.I. 312 at 3.) Neither the 2001 nor the 2004 exchange of letters led to licensing discussions. (*Id.*)

In August 2004, Kodak retained the law firm of Roylance, Abrams, Berdo and Goodman LLP ("Roylance") to provide an opinion on whether Kodak's products infringed the '121 patent. (D.I. 275 at 3; D.I. 312 at 4.) On October 21, 2004, Ampex filed an action against Kodak in the International Trade Commission ("ITC"), asserting infringement of the '121 patent. (D.I. 312 at 4.) On that same day, Ampex filed its complaint in this court (D.I.1), but its suit here was stayed pending resolution of the ITC action. (D.I.29.) A few weeks later, in November, Roylance provided to Kodak an oral opinion of non-infringement, which was later confirmed in a final written opinion to the same effect in September of

2005. (D.I. 312 at 4; *see also* D.I. 275 at 3-4.) In the meanwhile, on July 29, 2005, Ampex moved to withdraw its ITC complaint, which was then dismissed on August 23, 2005. (D.I. 312 at 4-5.) Consequently, the stay in this case was lifted. (*See* D.I. 33.)

Standard of Review

*2 A district court's determination as to the scope of the waiver of the attorney-client privilege is reviewed under an abuse-of-discretion standard. *In re EchoStar Communications Corp.*, 448 F.3d 1294, 1300 (Fed.Cir.2006) (citing *In re Pioneer,* 238 F.3d at 1373 n. 2 ("[I]t appears that virtually all the circuits review the decision of a district court [regarding waiver of privilege] underlying a petition for writ of mandamus for abuse of discretion.")).

Discussion

Relying on the Federal Circuit's recent opinion in *In re EchoStar, supra,* 448 F.3d 1294, Ampex argues that an advice-of-counsel defense in a patent case effects a wholesale waiver of privilege as to any communication that any attorney has with a client, so long as the communication touches on the same topic as the opinion on which the client relies to defend against a charge of willfulness. (*See* D.I. 268 at 2-3.) According to Ampex, it matters not when or in what context the subsequent communication occurs. Citing *Akeva L.L.C. v. Mizuno Corp.*, 243 F .Supp.2d 418 (M.D.N.C.2003), a case also cited by the Federal Circuit in its *Echostar* opinion, Ampex contends that there is no temporal limitation on the waiver of privilege, if infringing activity continues, nor is there any distinction between advice received from trial counsel and that received from opinion counsel. Ampex asserts that the *Echostar* opinion, in conjunction with *Akeva,* makes everything fair game for discovery, including communications between trial counsel and client during trial. (*See id.;* 5/11/06 Tr. at 9-12.) [FN3]

FN3. Citations to "5/11/06 Tr. at __" are to pages of the transcript of the May 11, 2006 teleconference in this matter. In subsequent briefing, Ampex backed off its we-get-every-communication argument to a degree, saying that *Echostar's* "core holding" is that discovery should not be permitted as a sword and a shield and that that principle is sufficient to require disclosure of trial counsel's communication in this case. (*See* D.I. 275 at 2.) Nevertheless, the logic of Ampex's position remains the same, whether or not Ampex chooses to go all the way to the logical limit, as the following exchange demonstrates:

> The Court:-is the short answer to my question, yes, that ... your reading of *Echostar* is that the Federal Circuit has now stated that the patentee is entitled to go after discovery all the way through trial. Any time trial counsel is talking to their client about infringement, they're entitled to know about it. [Counsel for Ampex]: That is what the Federal Circuit has stated, but we don't have to address that issue in this case.
>
> (*See* 5/11/06 Tr. at 11-12.)

I am compelled to reject Ampex's reading of *Echostar* as far too broad and its motion as an extravagant demand at odds with the generally understood contours of the attorney-client privilege.

To begin with, *Echostar* is, as I read it, an opinion aimed primarily at clarifying the scope of waiver of work product protection in the context of patent infringement cases involving an advice-of-counsel defense. The opinion gives clear and helpful direction on that difficult subject. It has less to say about the attorney-client privilege because that apparently was not the primary issue before the court. Perhaps that is why the court addressed the attorney-client privilege issue in relatively broad language, reasserting general principles. *Cf. Indiana Mills & Mfg., Inc. v. Dorel Indus., Inc.*, No. 04CV001102-LJM-WTL, 2006 WL 1749413, *7, n. 2 (S.D.Ind. May 26, 2006) (noting that "the *Echostar* court paints with a broad brush" when discussing the attorney-client privilege). For example, *Echostar* states that the attorney-client privilege cannot be used as a sword and a shield. 448 F.3d at 1301. That is a fundamental and well-understood rule, since, "selective waiver of the privilege may lead to the inequitable result that the waiving party could waive its privilege for favorable advice while asserting its privilege on unfavorable advice." *Id.* It is in the context of that general observation that the *Echostar* court made the comment so heavily relied on by Ampex here: "To prevent such abuses, we recognize that when a party defends its actions by disclosing an attorney-client communication, it waives the attorney-client privilege as to all such communications regarding the same subject matter." *Id.*

*3 Ampex seems to ignore both the context of that remark and its exact language. As to the language chosen, the *Echostar* court's use of the word "such" to modify the phrase "communications regarding the same subject matter" indicates that the court intended a far more limited meaning for its statement than Ampex wishes to give it. The use of "such" leads one back to earlier language in that portion of the opinion, in which the court is emphasizing the unfairness of allowing a party to hold back an attorney's opinion that is inconsistent with a different opinion it chooses to show the world. *See id.* The modifier "such" thus strongly implies that the type of communications being discussed are opinions expressed in a manner comparable to the opinion that is disclosed, as was apparently the case in *Echostar* itself.

The context includes not only the sentences surrounding the one Ampex fixes on, but also includes the factual background in *Echostar*. The defendant in that case wanted to rely on its inside counsel's opinion on infringement, while cloaking with privilege an outside opinion it had obtained on the same subject. It is hardly surprising that the court, given those facts, would call that maneuver a foul. The court was knocking down the defendant's artificial and unpersuasive distinction between inside and outside counsel. Nothing in that context, however, indicates a desire by the Court of Appeals to have every communication a client has with its trial counsel on the very subject of an infringement trial open to review by opposing counsel.

This is not elevating form over substance, as Ampex implies. (D.I. 275 at 8-9.) It is not the form of the communication that matters, it is the content. If one received advice of non-infringement and also received an opinion on that same topic from another attorney, it would not matter on the question of waiver how the communication was labeled. But, if all attorney-client discussions touching on the same subject were to be viewed as "advice" or "opinions" on a par with the legal opinions that were at issue in *Echostar,* the court's comments would have to be understood as demolishing the practical significance of the attorney-client privilege, a result obviously at odds with other comments in *Echostar, see* 448 F.3d at 1300-01 ("We recognize the privilege in order to promote full and frank communication between a client and his attorney so that the client can make well-informed legal decisions and conform his activities to the law."), and with other emphatic pronouncements of the Federal Circuit regarding the privilege, *see* *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1344 (Fed.Cir.2004) ("There should be no risk of liability in disclosures to and from counsel in patent matters; such risk can intrude upon full communication and ultimately the public interest in encouraging open and confident relationships between client and attorney."). It will take more than the inference Ampex wants to draw from *Echostar* to persuade me that the Federal Circuit intends a wholesale revision of the historical understanding of the attorney-client privilege.

*4 *Echostar* did not even address the issue of communications with trial counsel. To try to stretch the opinion to cover its position here, Ampex notes that *Echostar* cites the *Akeva* case, which did deal with trial counsel communications. (D.I. 275 at 5.) What Ampex ignores is that *Akeva* dealt with circumstances in which the defendant expressly relied on its trial counsel's non-infringement opinion to continue operating, while awaiting a separate opinion from another source. *Akeva,* 243 F.Supp.2d at 419-20. That is not akin to the facts in this case.[FN4]

> FN4. I emphasize that the present case does not involve a party choosing to use an attorney as both opinion counsel and trial counsel. That choice involves an unfortunate blending of roles that is, thankfully, rare and beyond the discussion provided here.

Finally, Ampex tries to justify its extraordinary waiver argument by saying that Kodak waited to obtain an opinion until after litigation had begun. That argument appears to rest on an erroneous factual assertion and, in any event, it assumes that trial counsel was providing non-infringement opinions in the interim. In the particular history of this case, Kodak asserts that it had a non-infringement opinion from its in-house counsel three years before any litigation commenced. (D.I. 312 at 3.) Before litigation began, Kodak sought from outside counsel an opinion regarding infringement. (*Id.* at 4; D.I. 275 at 3-4.) That opinion was provided orally shortly after suit was filed. (D.I. 312 at 4.) Ampex chose to proceed first in the ITC, where neither damages nor willfulness were at issue, so Kodak chose not to press for a written opinion (*see id.*)-a logical choice, since the purpose of the advice-of-counsel defense in infringement litigation is typically to avoid enhanced damages. I thus fail to see anything nefarious in Kodak getting its written opinion from outside counsel only after Ampex abandoned its ITC case and reinitiated its claims, including damages claims,

in this court. Under these facts, Ampex has failed to demonstrate that Kodak's obtaining a further written opinion from its opinion counsel is somehow a cover for non-infringement advice it was actually getting from its trial counsel.

Conclusion

For the foregoing reasons, it is hereby ORDERED that the bench ruling of July 13, 2006 is confirmed and the Motion (D.I.268) is DENIED.

D.Del.,2006.
Ampex Corp. v. Eastman Kodak Co.
Slip Copy, 2006 WL 1995140 (D.Del.)

Briefs and Other Related Documents (Back to top)

- 2006 WL 1813962 (Trial Motion, Memorandum and Affidavit) Ampex's Reply Brief in Support of its Motion to Compel (May 31, 2006) Original Image of this Document (PDF)
- 2006 WL 1813961 (Trial Pleading) Ampex Corporation's Opening Claim Construction Brief (May 23, 2006) Original Image of this Document (PDF)
- 2006 WL 1813960 (Trial Motion, Memorandum and Affidavit) Ampex's Opening Brief in Support of its Motion to Compel Disclosure of Withheld Communications and for Production of A Privilege Log (May 18, 2006) Original Image of this Document (PDF)
- 2006 WL 1199897 (Trial Motion, Memorandum and Affidavit) Defendant's Redactted Reply Brief in Further Support of their Motion to Disqualify Eric Anderson as an Expert Witness (Mar. 31, 2006) Original Image of this Document (PDF)
- 2006 WL 1199896 (Trial Motion, Memorandum and Affidavit) Defendants' Reply Brief in Further Support of their Motion to Bifurcate and Motion for Protective Order (Mar. 15, 2006) Original Image of this Document (PDF)
- 2006 WL 1199895 (Trial Motion, Memorandum and Affidavit) Defendants' Redacted Opening Brief in Support of its Motion to Disqualify Eric Anderson as an Expert Witness (Mar. 13, 2006) Original Image of this Document (PDF)
- 2006 WL 809152 (Trial Motion, Memorandum and Affidavit) Defendants' Opening Brief in Support of their Motion for Bifurcation and Protective Order (Feb. 22, 2006) Original Image of this Document (PDF)
- 2005 WL 3666894 (Trial Motion, Memorandum and Affidavit) Protective Order for Confidentiality (Nov. 1, 2005) Original Image of this Document (PDF)
- 2005 WL 3666892 (Trial Pleading) Ampex's Reply to Altek Corporation's Counterclaims (Oct. 12, 2005) Original Image of this Document (PDF)
- 2005 WL 3666893 (Trial Pleading) Ampex's Reply to Eastman Kodak Company and Chinon Industries Inc.'s Counterclaims (Oct. 12, 2005) Original Image of this Document (PDF)
- 2005 WL 2868003 (Trial Pleading) Altek Corporation'S Answer to Second Amended Complaint for Patent Infringement (Sep. 22, 2005) Original Image of this Document (PDF)
- 2005 WL 2868006 (Trial Pleading) Eastman Kodak Company and Chinon Industries Inc. (N/K/A Kodak Digital Product Center Japan, Ltd)'s Answer to Second Amended Complaint for Patent Infringement (Sep. 22, 2005) Original Image of this Document (PDF)
- 2005 WL 2603825 (Trial Pleading) Second Amended Complaint for Patent Infringement (Sep. 8, 2005) Original Image of this Document (PDF)
- 2005 WL 3242229 (Trial Pleading) Second Amended Complaint for Patent Infringement (Sep. 8, 2005) Original Image of this Document (PDF)
- 1:04cv01373 (Docket) (Oct. 21, 2004)

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EXHIBIT CC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES, LTD, and SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS U.S.A., INC., Defendant.	Civil Action No: 05-197 GMS

DEFENDANT TEVA PHARMACEUTICALS U.S.A., INC.'S THIRD SUPPLEMENTAL RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES

Pursuant to Federal Rules of Civil Procedure 26 and 33, Defendant Teva Pharmaceuticals U.S.A., Inc. ("Teva") hereby provides supplemental responses to Plaintiffs' First Set of Interrogatories. Teva reserves the right to further supplement or amend its responses as it obtains additional information during the course of discovery.

GENERAL OBJECTIONS

Teva incorporates each of the objections set forth in its original and supplemental Responses to Plaintiffs' First Set of Interrogatories as if explicitly set forth herein. Those objections are hereby incorporated into each of Teva's supplemental responses as if fully set forth therein.

privileged work product and attorney-client communications. Subject to its general and specific objections, Teva supplements its original response as follows.

Teva identifies Scott Stofik, Deborah Jaskot, and John Kovaleski as individuals involved in the development and manufacture of the drug products identified in Teva's ANDA No. 77-460. Mr. Stofik is a Senior Scientist II in Teva's Generic Research & Development who oversaw the development of the drug products identified in Teva's ANDA No. 77-460. Ms. Jaskot, Teva's Vice President of Regulatory Affairs, and Ms. Capresi, Senior Associate, Regulatory Affairs, both participated in the development of the drug products identified in the ANDA by way of regulatory submissions and/or communications regarding the same. Mr. Kovaleski is Teva's Director of Analytical Research and Development. In addition, pursuant to Federal Rule of Civil Procedure 33(d), additional individuals, if any, may be derived from the following documents: TEV-RQ 000001-006503. Additional individuals may be identified from any further documents that Teva will produce or make available in response to GSK's requests for production of documents and tangible things. Teva reserves the right to further supplement its response as it obtains additional information during the course of discovery consistent with the Federal Rules, Local Rules, and the Court's Scheduling Order. Teva further identifies each of the witnesses that Teva has made available for deposition by GSK, either in their individual or representative capacity, and incorporates by reference their testimony regarding the identification of individuals who were "involved in any way in developing or manufacturing Teva's Proposed Products, including the decision(s) to develop or manufacture Teva's Proposed Products."

INTERROGATORY NO. 3:

State with particularity each and every legal and factual basis for Teva's allegations that the '808 patent is unenforceable or invalid under 35 U.S.C. §§ 101, 102, 103, 112 and 116. The detailed description should include, without limitation, an identification of each statute, judicial or administrative decision, document, tangible item, item of information, piece of prior art, and fact that Teva relied upon in preparing its Answer and Counterclaims, that Teva relied upon in

preparing the Certification Letter or the Teva ANDA, and/or that Teva intends to rely upon as support for its allegations that the '808 patent is unenforceable and/or invalid.

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory as improperly being characterized as one interrogatory because its many subparts constitute separate interrogatories towards the 50 interrogatory limit. *See* D. Del. LR 26.1(b). Teva further objects to this Interrogatory as premature to the extent that it purports to seek expert discovery in advance of the time provided by the Court's Scheduling Order and to the extent that responding to this Interrogatory requires the input of an expert witness(es). Teva reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and Court's Scheduling Order. Furthermore, Teva also expressly reserves the right to supplement its response to this Interrogatory to the extent that Plaintiffs respond with, or are permitted to change or otherwise supplement, their contentions set forth in response to Teva's interrogatories on the issue of patent invalidity. *See, e.g.*, Defendant Teva Pharmaceuticals U.S.A., Inc.'s Interrogatory No. 7 to Plaintiffs GlaxoSmithKline.

Subject to its general and specific objections, Teva responds to the Interrogatory as follows with reference to each individual topic identified in the interrogatory:

(1) Claims 1-5 and 8-12 of the '808 patent are invalid as obvious under 35 U.S.C. §103 in view of the combination of U.S. Patent No. 4,314,944 and at least one of the following references:

(a) Cannon, J.G., Hsu, F., Long, J.P., Flynn, J.R., Costall, B. and Naylor, R.J., "*Preparation and Biological Actions of Some Symmetrically N, N-Disubstituted Dopamines*," J. Med. Chem., 1978, Vol. 21, No. 3: 248-253 ("Cannon 1978 article");

(b) Cannon, J.G., "*Dopamine Congeners Derived from Benzo(f) quinolone Ring*," Advances in Biosciences, 1979, Vol. 20: 87-94 ("Cannon 1979 article");

(c) Cannon, J.G., Demopoulos, B.J., Long, J.P., Flynn J.R. and Sharabi, F.M., "*Proposed Dopaminergic Pharmacophore of Lergotrile, Pergolide, and Related Ergot Alkaloid Derivatives*," J. Med. Chem. - Communications to the Editor, 1981, Vol. 24: 238-240 (1981) ("Cannon 1981 article I");

(d) Cannon, J.G., Long, J.P. and Bhatnagar, R., "*Future Directions in Dopaminergic Nervous System and Dopaminergic Agonists*," J. Med. Chem., 1981, Vol. 24, No. 10: 1113-1118 ("Cannon 1981 article II");

(e) Geissler, H.E., "*3-[2-(Dipropylamino)ethyl]phenol: a new and selective dopaminergic agonist*," Arch. Pharm. (Weinheim) Vol. 310: 749-756 (1977) ("Geissler 1977 article");

(f) Walker, J., Daisley, R.W. and Beckett, A.H., "*Substituted Oxindoles. III. Synthesis and Pharmacology of Some Substituted Oxindoles*," J. Med. Chem., 1970, Vol. 13, No. 5: 983-985 ("Walker 1970 article");

(2) Claims 1, 2 and 6-8 of the '808 patent are invalid under 35 U.S.C. § 101 for failure to show that all of the compounds embraced within the scope of these claims are useful for the purpose intended, and/or under 35 U.S.C. § 112 for failure to describe how to make and use each of the claimed compounds and for failure to satisfy the written description requirement. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article.

(3) Claims 1, 2 and 6-8 of the '808 patent are invalid under 35 U.S.C. § 116 and 256 for failure to correctly join the individual(s) responsible for conceiving of the alleged invention(s) claimed therein and are further invalid under 35 U.S.C. § 102(f) and (g) because the alleged invention(s) claimed therein was invented by another, rather than solely by Mr. Gallagher.

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(4) Claims 8-12 of the '808 patent are invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation the size of a nontoxic D_2 receptor agonist quantity of each of the claimed compounds upon administration to a human being. A person of ordinary skill in the art would understand that

non-routine testing would be necessary to derive effective, non-toxic human doses from animal testing results. Particularly with respect to claim 11, the specification also fails to teach a person of ordinary skill in the art how to make and use compositions including each of the claimed compounds to as antihypertensive agents. Furthermore, with respect to claim 12, the specification also fails to teach a person of ordinary skill in the art how to make and use compositions including each of the claimed compounds in amounts over the entire recited dose range. Teva intends to rely upon, among other things, Plaintiffs' own dose response and toxicity testing for ropinirole and other compounds in support of this invalidity defense.

(5) The '808 patent and all of the claims therein are unenforceable for inequitable conduct,

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REDACTED Mr. Gallagher's submission of his false inventorship declaration is presumptively material, and in any case, Mr. Gallagher either knew or should have known that his false statements regarding sole inventorship would be material to the patentability of the alleged claimed invention(s).

REDACTED

Mr. Gallagher submitted his false inventorship declaration to the U.S. Patent & Trademark Office with the intent to deceive the Patent Office and convince the Patent Office to issue the '808 patent.

(6) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification misstates that one of the claimed compounds, ropinirole, was shown to "not cause tachyphylaxis in the [perfused hind limb] preparation as did its 7-hydroxy congener of the prior art" and that this is a proper basis for inferring that the remaining claimed compounds also "may not be subject to tachyphylaxis." Putative sole inventor Gregory Gallagher signed his inventorship declaration stating that he had reviewed the patent specification and that all of the statements in the '808 patent application were true, but at the time he signed that declaration, Mr. Gallagher had not confirmed the accuracy of those statements in the '808 patent specification regarding ropinirole's lack of tachyphylaxis effects. Mr. Gallagher falsely vouched for this statement in the patent specification with the intent to deceive the Patent Office and convince it to accept GSK's assertions in the '808 patent that ropinirole (and the other claimed compounds) had more selective activity and improved physiological characteristics from compounds known in the prior art. Alternatively or in addition thereto, an individual(s) who should have properly

been named as a joint inventor for the '808 patent or who was involved in preparation or prosecution of the '808 patent application knew that the '808 patent specification statements regarding tachyphylaxis were false, and that individual(s) permitted the '808 patent application to be submitted to the Patent Office with the aforementioned false statements with the intent to deceive the Patent Office and convince it to accept GSK's assertions in the '808 patent that ropinirole had more selective activity and improved physiological characteristics from compounds known in the prior art. The submission of these false statements to the Patent Office is inherently material, and the '808 patent specification's statements differentiating the alleged invention(s) claimed in the '808 patent from compounds known in the prior art made these false statements to the Patent Office explicitly material.

(7) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification wrongly suggests that one of the claimed compounds – ropinirole hydrochloride – was tested to determine an effective dose "to show anti-hypertensive activity" in "an average size human."

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The statements in the '808 patent

implying that the disclosed dosage range was effective to cause anti-hypertensive effects in humans by administering ropinirole hydrochloride were materially false. These speculative dose ranges would have been misconstrued by a reasonable Patent Office examiner as supporting the enablement of some or all of the alleged claimed inventions, at least in part.

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Mr. Gallagher and other individuals involved in the prosecution of the '808 patent intended to deceive the Patent Office by allowing the '808 patent application to be submitted to the Patent Office with these statements suggesting that an effective dose range for ropinirole hydrochloride had been determined.

(8) The '808 patent and all of the claims therein are unenforceable for inequitable conduct, because at least one individual who should have been named as a joint inventor with respect to the alleged invention(s) claimed in the '808 patent, J. Paul Hieble, knew of at least one material prior art reference – the Cannon 1981 article I – and had a duty to disclose material prior art references to the Patent Office. The Cannon 1981 article I discloses a structurally similar compound to ropinirole and describes that compound as having both cardiovascular and CNS dopamine-agonist effects when administered in animal models. Rather than disclose that material prior art to the Patent Office, GSK, and, particularly, putative sole inventor Gregory Gallagher, intentionally omitted Mr. Hieble from the list of inventors for the '808 patent with the intent to deceive the Patent Office and prevent the disclosure of material prior art to the Patent Office during the examination of the '808 patent application.

INTERROGATORY NO. 4:

State with particularity each and every legal and factual basis for Teva's allegations that the '860 patent is unenforceable or invalid under 35 U.S, C. §§ 101, 102, 103, 112 and 116. The detailed description should include, without limitation, an identification of each statute, judicial

or administrative decision, document, tangible item, item of information, piece of prior art, and fact that Teva relied upon in preparing its Answer and Counterclaims, that Teva relied upon in preparing the Certification Letter or the Teva ANDA, and/or that Teva intends to rely upon as support for its allegations that the '860 patent is unenforceable and/or invalid.

THIRD SUPPLEMENTAL RESPONSE:

Teva objects to this Interrogatory as improperly being characterized as one interrogatory because its many subparts constitute separate interrogatories towards the 50 interrogatory limit. *See* D. Del. LR 26.1(b). Teva notes that no claim terms, phrases, or clauses of the asserted claims have yet been construed by the Court nor have Plaintiffs provided Teva with Plaintiffs' contentions as to the proper construction of any disputed claim terms, phrases, or clauses. Claim construction, which is an issue for the Court, is the first step in an infringement and/or invalidity analysis. Teva further objects to this Interrogatory as premature to the extent that it purports to seek expert discovery in advance of the time provided by the Court's Scheduling Order and to the extent that responding to this Interrogatory requires the input of an expert witness(es). Teva reserves the right to supplement this response on this basis and on the basis of any additional discovery consistent with the Federal Rules of Civil Procedure, the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, and Court's Scheduling Order. Furthermore, Teva also expressly reserves the right to supplement its response to this Interrogatory to the extent that Plaintiffs respond with, or are permitted to change or otherwise supplement, their contentions set forth in response to Teva's interrogatories on the issue of patent invalidity. *See, e.g.*, Defendant Teva Pharmaceuticals U.S.A., Inc.'s Interrogatory No. 7 to Plaintiffs GlaxoSmithKline.

Subject to its general and specific objections, Teva responds to the Interrogatory as follows with reference to each individual topic identified in the interrogatory:

(1) All claims (claims 1-3) of the '860 patent are invalid as having been invented by another. For example, the alleged claimed invention(s) are anticipated under 35 U.S.C. § 102(f) and/or (g) in view of the report entitled "SK&F 101468-A: a centrally acting dopamine agonist having antiparkinson, antidepressant and anxiolytic activity. A neuropharmacological study: Part 1," written by Professors Brenda Costall and R. J. Naylor of the University of Bradford and submitted to Dr. David Owen, the sole "inventor" named on the face of the '860 patent, in September 1986 ("Costall et al. 1986 report"). The Costall et al. 1986 report discloses that ropinirole can be used to treat Parkinson's Disease, specifically stating that "SK&F 101468-A [*i.e.* ropinirole] thus presents a novel dopamine agonist having antiparkinson, antidepressant and anxiolytic potential. ... It would be interesting, therefore, to determine the clinical efficacy of SK&F 101468-A or a related compound in Parkinson's disease ...." (GSK-REQ001062-63.)

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Moreover, even if Dr. Owen arrived at his "hypothesis" prior to receiving the Costall et al. 1986 report, that hypothesis was insufficient to constitute conception of the alleged invention(s) claimed in the '860 patent, as it did not evidence a definite and permanent idea that ropinirole could be used to treat human patients with Parkinson's disease. The evidence shows that Dr. Owen was not an inventor, or at least was not the sole inventor, of the alleged claimed invention(s) and that any alleged invention(s) claimed in the '860 patent were actually invented wholly or in part by Professors Brenda Costall and R.J. Naylor of the University of Bradford.

(2) All claims of the '860 patent are invalid as obvious, under 35 U.S.C. §103 in view of the '808 patent and/or '944 patent in combination with at least one of the following references:

(a) the Cannon 1978 article;

(b) the Cannon 1979 article;

(c) the Cannon 1981 article I;

(d) the Cannon 1981 article II;

(e) Cannon, J.G., "*The Design of Potential Anti-Parkinson Drugs: What is the Dopaminergic Pharmacophore in Ergot Alkaloids?*," Proc. Iowa Acad. Sci. 93(4):169-174, 1986 ("Cannon 1986 article");

(f) the Geissler 1977 article;

(g) Gallagher, Jr., G., Lavanchy, P.G., Wilson, J.W., Hieble, J.P. and DeMarinis, R.M., "*4-[2-(Di-n-propylamino)ethyl]-2(3H)-indolone: A Prejunctional Dopamine Receptor Agonist*," J. Med. Chem. 1985, Vol. 28:1533-1536;

(3) Claim 1 of the '860 patent is invalid under 35 U.S.C. § 101 for failure to show how each of the compounds embraced within the scope of these claims can be administered to a patient suffering from Parkinson's disease to treat that condition and/or under 35 U.S.C. § 112 for failure to describe the alleged invention(s) claimed in the '860 patent and how to practice the claimed method of treating Parkinson's disease by administering each of the claimed compounds. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article, and internal GSK testing of a compound other than ropinirole

that is described one combination of substituents in the general chemical structure recited in claim 1 of the '860 patent showed that this other compound lacked dopaminergic activity.

(4) Claims 1-3 of the '860 patent are also invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation what an "effective non-toxic amount" of a claimed compound that is effective to treat conditions of Parkinson's Disease in a human being. A person of ordinary skill in the art would understand that non-routine testing would be necessary to derive effective, non-toxic human doses from animal testing results. Teva intends to rely upon, among other things, Plaintiffs' own dose response and toxicity testing for ropinirole and other compounds in support of this invalidity defense.

(5) Claim 1 of the '860 patent is also invalid under 35 U.S.C. § 112 ¶ 1 for failure to enable a person of ordinary skill in the art to determine without undue experimentation how to administer an "effective non-toxic amount" of any claimed compound other than ropinirole in a manner that is effective to treat conditions of Parkinson's Disease in a human being. A person of ordinary skill in the art would not assume that all of the claimed compounds have the stated physiological effects when administered to patients based on experimental results related to the administration of only ropinirole, as the prior art disclosed that changes in the reactive groups of these compounds could greatly affect their activity, *e.g.* the Cannon 1979 article.

(6) Claim 1 of the '860 patent is invalid under 35 U.S.C. § 116 and/or 256 for failure to properly join all inventor(s) of the entire alleged invention(s) claimed.

REDACTED

REDACTED

REDACTED

As a result, GSK cannot move to correct the mistaken inventorship of the '860 patent, because GSK cannot identify the other individual(s) responsible for conceiving of portions of the alleged claimed invention(s) covering compounds other than ropinirole or its hydrochloride salt. Furthermore, the evidence of record demonstrates that Professors Costall and Naylor, not Dr. Owen, first conceived of the definite and permanent idea of using ropinirole to treat Parkinson's disease. As a result, the '860 patent is invalid.

(7) The '860 patent and all of the claims therein are unenforceable for inequitable conduct, because putative sole inventor David A.A. Owen admitted that the only compound he conceived of administering to a patient suffering from Parkinson's disease in order to treat that condition was 4-(2-di-n-propylaminoethyl)-2(3H)-indolone ("ropinirole") or its hydrochloride salt, and that he neither conceived of using any of the other compounds

covered in claim 1 of the patent for treating Parkinson's disease nor believed that the compounds of claim 1 shared common structural features such that all of the claimed compounds would exhibit similar effectiveness in treating Parkinson's disease upon administration.

REDACTED

Furthermore, Dr. Owen did not even first conceive the alleged claimed invention of using ropinirole or its hydrochloride salt to treat Parkinson's disease, as the idea that ropinirole could be used to treat Parkinson's disease was first proposed in a September 1986 report received by Dr. Owen from Professors Brenda Costall and R.J. Naylor of the University of Bradford.

REDACTED

At the time he submitted the declaration, Dr. Owen knew that his assertion of sole inventorship was false. Dr. Owen's submission of his false inventorship declaration is presumptively material, and in any case, Dr. Owen either knew or should have known that his false statements regarding sole inventorship would be material to the patentability of the alleged claimed invention(s).

REDACTED

(8) The '860 patent and all of the claims therein are unenforceable for inequitable conduct, because the specification mischaracterizes the prior art bromocriptine compound as a "post-synaptic dopamine agonist." GSK's own researchers – including, for example, in Robert M. DeMarinis, *et al.*, "Syntheses and In-Vitro Evaluation of 4-(2-Aminoethyl)-2(3H)-indolones and Related Compounds as Peripheral Prejunctional Dopamine Receptor Agonists," J. Med. Chem. 29:939-947 (1986) – had previously published articles indicating that bromocriptine was a pre-synaptic dopamine agonist, rather than a post-synaptic dopamine agonist. The '860 patent specification falsely indicates that the anti-Parkinsonian activity of the claimed compounds, including ropinirole, is the result of its post-synaptic, rather than pre-synaptic, site of action, and cites the prior art bromocriptine compound as an example of knowledge among those of ordinary skill in the art that only post-synaptically active dopamine agonists could be used to treat Parkinson's disease. Moreover, Dr. Owen, a co-author of the aforementioned paper by DeMarinis *et al.* did not disclose that material prior art to the Patent Office, which would have allowed the Patent Office examiner to independently discover the false statements in the '860 patent regarding the site of action of the prior art bromocriptine compound. A reasonable Patent Office examiner would have considered the prior art knowledge that bromocriptine acted at a pre-synaptic site of action and the DeMarinis *et al.* paper material to patentability, because the pre-synaptic activity of ropinirole was, as admitted in the '860 patent specification, well-known in the art. The false statement in the '860 patent were brought to the attention of GSK patent attorneys or agents involved in the prosecution of the '860 patent application during its pendency in connection with the prosecution of one of GSK's corresponding foreign patent applications, but neither GSK nor Dr. Owen took steps to correct the false statement in the '860 patent specification.

Accordingly, Dr. Owen and other individuals at GSK involved in the prosecution of the '860 patent application intentionally withheld from the Patent Office information material to the patentability of the alleged invention(s) claimed in the '860 patent and did so with the intent to deceive the Patent Office and convince it to issue the '860 patent.

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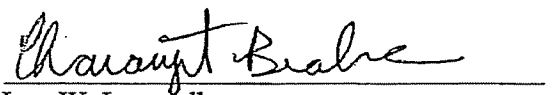
Respectfully submitted,



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